

REMARKS

Claims 57-61 were pending. Claims 57-61 have been cancelled herein without prejudice. New claims 67-69 have been added. Support for new claim 67 may be found in the subject matter of cancelled claims 57 and 58 and on page 31, lines 1-4 of the specification. New Claims 68 and 69 correspond to cancelled claims 59 and 61, respectively, and replace these claims so that the dependent claims follow the claim from which they depend. Thus, claims 67-69 are currently pending. No new matter has been added.

In the August 4, 2009 Final Office Action the Examiner rejected the claims as follows:

1. Claims 57-61 are rejected under 35 U.S.C. § 112, ¶1, as allegedly failing to comply with the written description requirement;
2. Claims 57-61 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Sweeney et al (hereinafter “Sweeney”) in combination with U.S. 5,747,536 (hereinafter “Cavazza”) and Ogawa et al (hereinafter “Ogawa”) and Tegos et al (hereinafter “Tegos”).
3. Claims 57-61 are provisionally rejected on the ground on nonstatutory obviousness-type double patenting as allegedly being obvious over claims 57-61 of copending Application Serial No. 11/770,136.

Applicant respectfully traverses these rejections.

Claim Rejections under 35 U.S.C. § 112, first paragraph

Claim 57 has been cancelled hereinabove and the subject matter of new claim 67 finds support, *inter alia*, in the Table on page 31 of the specification. Claim 67 now recites a concentration of L-carnitine of 0.25 to 50 mM and specifies that effective storage can be up to 8 days. Accordingly, the cancellation of claim 57 and the addition of new claim 67 (which is fully

supported by the specification) render the rejection under 35 U.S.C. § 112, ¶1 moot. Thus, withdrawal of this rejection is respectfully requested.

Claim Rejections under 35 U.S.C. § 103(a)

The cited references have been discussed at length during the prosecution of the present application. Applicant incorporates by reference the previously submitted arguments and adds the following additional arguments.

As discussed in more detail below, none of the cited references, alone or in any combination, disclose, teach or suggest a method for suppressing bacterial growth in a blood fraction, which method includes, *inter alia*, the step of: leuko-reducing the platelet concentrate in said blood fraction to form a prestorage leuko-reduced platelet concentrate unexpectedly which provides effective storage for up to 8 days. In fact, as discussed in more detail below, these references taken together actually teach away from the presently pending claims.

The Examiner cites Sweeney as the primary reference. A close examination of Sweeney, however, shows that the reference merely describes that addition of saline, L-carnitine or L-acetylcarnitine at 5 mM to platelet concentrate provides better preservation of pH, less glucose consumption and lactate production through 5 days of storage. Indeed, Sweeney describes the use of standard, non-leuko-reduced platelet concentrates.

In sharp contrast, new claim 67 recites the step of leuko-depleting the platelet concentrates. This step is completely absent in Sweeney and unexpectedly results in the ability to effectively store such platelet concentrates for up to 8 days. The Table on page 31 of the Applicant's specification confirms these storage results which are far superior to those described by Sweeney.

Thus, Sweeney alone (as conceded by the Examiner) cannot render obvious the claimed subject matter.

Importantly, none of Cavazza, Ogawa and Tegos remedy the deficiencies of Sweeney discussed above.

With respect to Cavazza, Applicant first notes that the compositions disclosed therein are directed to the treatment of cardiovascular disorders, peripheral vascular diseases and peripheral diabetic neuropathy. To rely on a reference under 35 U.S.C. § 103, the reference must be analogous to the subject matter at issue (See *e.g.*, MPEP § 2141.01(a)). Applicant point out that the treatment of cardiovascular disorders, peripheral vascular diseases and peripheral diabetic neuropathy is not analogous subject matter vis-à-vis the presently claimed methods directed to extending effective platelet concentrate storage up to 8 days.

Thus, a person of ordinary skill in the art corresponding to the methods according to the present invention would not look to references describing methods of treatment of cardiovascular disorders, peripheral vascular diseases and peripheral diabetic neuropathy. Accordingly, such a skilled artisan would not address his/her attention to Cavazza for information concerning platelet storage. Therefore, Applicant submits that Cavazza as non-analogous art cannot be used to cure the deficiencies of Sweeney.

But even if Cavazza were considered analogous art, it still does not cure the deficiencies of Sweeney. Cavazza does not describe or suggest the inclusion of a leuko-depleting step in a method for providing effective storage of platelet concentrate up to 8 days. As with Sweeney, the Examiner conceded that Cavazza does not address this claim limitation.

Ogawa also fails to cure the deficiencies of Sweeney and Cavazza. Ogawa merely states that prestorage leukocyte filtration reduces the severity of post-transfusion side effects and describes a 3-day storage period, a period which is even shorter than the storage period disclosed in Sweeney.

Similarly, Tegos fails to remedy the deficiencies of Sweeney, Cavazza and Ogawa. Tegos simply describes that platelet concentrates can be stable for up to 3 days, which, like Ogawa, is a storage period even shorter than the 5 days disclosed in Sweeney (See, Tegos, p. 203, first column).

Accordingly, a person of ordinary skill in the art would not find any motivation in Ogawa or Tegos to add a leuko-depletion step to the method disclosed in Sweeney since the storage time describe by Sweeney is longer than the storage time disclosed in Ogawa and Tegos. In other words, a person of ordinary skill in the art would believe that adding the leuko-depletion step to the Sweeney method would reduce the effective storage period. In this regard, the combination of Sweeney and Ogawa and/or Tegos teach away from the presently claimed invention. Accordingly, there is no suggestion or motivation in any of the secondary references to modify Sweeney to achieve the unexpected results of the presently claimed invention relating to methods for storing platelet concentrates up to 8 days.

Accordingly, as none of the cited references, either alone or in combination, discloses, teaches or suggests methods that allow for the effective storage of leuko-depleted platelet concentrates up to 8 days, it is respectfully submitted that the combination of the cited references would not have rendered obvious the claimed subject matter to one skilled in the art. Thus, withdrawal of the rejection of the pending claims under 35 U.S.C. § 103 (a) as being unpatentable is respectfully requested.

Obviousness-Type Double Patenting Rejection

Applicant submits herewith a terminal disclaimer applicable to co-pending Application Serial No. 11/770,136. Therefore, the nonstatutory obviousness-type double patenting rejection of claims 57-61 is now moot and Applicant respectfully requests withdrawal of this rejection.

Conclusion

In view of the foregoing, applicants respectfully request that the Examiner reconsider and withdraw the rejections raised in the August 4, 2009 Final Office Action and allow the presently pending claims, namely claims 67-69.

No fee other than the fee for the accompanying RCE and One-Month Extension of Time is believed to be due in connection with the filing of this Amendment. However, the Director is hereby authorized to charge any additional fee(s) deemed necessary or credit any overpayments to Deposit Account No. 02-2275.

If a telephone interview would be of assistance in advancing prosecution of this application, Applicant's undersigned attorney respectfully requests that the Examiner telephone him at the number provided below.

Respectfully submitted

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